

Attorney Docket No.: DEX-0271
Inventors: Macina et al.
Serial No.: 10/001,883
Filing Date: November 20, 2001
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REMARKS

Claims 1, 2, 4, 5, 7-9, 15, 18 and 19 are pending in the instant application. Claims 1, 2, 4, 5, 7-9, 15, 18 and 19 have been rejected. Claims 1 and 15 have been amended. Support for these amendments is provided in the specification in Examples 1 and 2 beginning at page 116 and page 11, line 21 through page 12, line 15. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claim 15 under 35 U.S.C. 112, second paragraph

The rejection of claim 15 under 35 U.S.C. 112, second paragraph has been maintained as the Examiner suggests that recitation of "means for determining the presence of the nucleic acid molecule of claim 1" is vague and indefinite.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 15 to specify that the kit comprises an oligonucleotide for determining the presence of a nucleic acid molecule of the present invention. Oligonucleotides for determining the

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presence of a nucleic acid molecule are described in the specification at page 11, line 21 through page 12, line 15. Further, oligonucleotides for detecting the presence of a defined nucleic acid molecule as in the present invention are used routinely by those of skill in the art. Thus, the claim is clear and definite when read in light of teachings of the specification and what is well known to those skilled in the art.

No new matter is added by this amendment.

Withdrawal of this rejection under 35 U.S.C. 112, second paragraph is respectfully requested.

**II. Rejection of Claims 1, 2, 4, 5, 7-9, 15, and 18-20
under 35 U.S.C. 112, first paragraph - Written Description**

Claims 1, 2, 4, 5, 7-9, 15 and 18-20 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner has applied this rejection to embodiments of claim 1(c) and 1(d), as the Examiner suggests that these embodiments cover a large genus of related nucleic acids which are not described and were not in Applicants possession. The Examiner acknowledges in paragraph 4 of the Office Action mailed 28 May 2004, however, that:

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it may be possible to claim a nucleic acid more broadly than a single disclosed species given a certain degree of identity of hybridization conditions and a function".

Similarly, MPEP § 2163 II.3.(a)ii. states:

The written description requirement for a claimed genus may be satisfied through . . . or by disclosure of relevant, identifying characteristics, . . . or by a combination of such identifying characteristics . . .

Any number or type of identifying characteristics may be disclosed to meet the written description requirement.

Thus, in an earnest effort to advance the prosecution of this case, Applicants have amended part (c) and (d) of claim 1 to include the identifying feature that said nucleic acid is differentially expressed in cancer. Applicants amendment of claim 1 clearly meets the written description requirement of 35 U.S.C. 112, first paragraph, as outlined in MPEP § 2163 II.3.(a)ii by disclosing a combination of relevant, identifying characteristics, namely, for Claim 1, part (c), a nucleic acid molecule which is differentially expressed in cancer AND which hybridizes under specifically defined stringent conditions to a nucleic acid molecule of (a) or (b) and for claim 1, part (d) a nucleic acid molecule which is differentially expressed in cancer AND has at least 75% sequence identity over its entire length to the nucleic acid molecule of (a) or (b).

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Claim 1, as amended incorporates the suggestion by the Examiner that an additional identifying characteristic (as defined by MPEP § 2163 II.3.(a)ii.) be included to meet the written description requirement for a nucleic acid molecule with a certain degree of identity or hybridization conditions.

This amendment is clearly supported by teachings of the specification, for example in Examples 1 and 2 beginning at page 116, wherein determination of differential expression of nucleic acid molecules of the present invention in cancer is outlined in detail. Thus, no new matter is added by this amendment.

Withdrawal of this rejection under 35 U.S.C. 112, first paragraph, is respectfully requested.

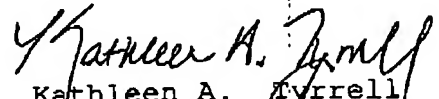
III. Conclusion

Applicants believe the above-described amendments overcome all rejections of the pending claims and that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable

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reconsideration and subsequent allowance of the pending
claims is earnestly solicited.

Respectfully submitted,


Kathleen A. Tyrrell
Registration No. 38,350

Date: August 30, 2004

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515

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